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C O N F I D E N T I A L SECTION 01 OF 03 MOSCOW 002533

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TAGS: TBIO SOCI ETRD RS

SUBJECT: RUSSIA BANS EXPORTS OF HUMAN BIOLOGICAL SPECIMENS

REF: A. MOSCOW 976

¶B. 06 MOSCOW 13072

¶C. 05 MOSCOW 13418

Classified By: EST Counselor Daniel J. O'Grady. Reason: 1.4(b,d)

¶11. (C) SUMMARY: The Federal Customs Service has temporarily banned all exports of human biological specimens from Russia, including hair, tissue, urine, and blood samples. According to press reports, the ban was imposed after an intelligence report to the Kremlin alleged that Western researchers who receive Russian samples are engaged in a program to develop "genetic biological weapons." The government's decision to impose an export ban appears to have been taken in haste, and without fully thinking through the impact on international scientific collaboration, on the tens of thousands of Russians in clinical trials for new medicines, or those needing life-saving organ or tissue transplants from abroad.
END SUMMARY.

Customs Service Bans Exports of Human Bio-Materials

¶12. (SBU) Russia's Federal Customs Service has banned the export of human biological specimens from Russia. According to press reports, the move came after a government intelligence report alleged that Western organizations who receive such samples are allegedly engaged in a program to develop "genetic biological weapons" that could harm the Russian population. One press report specifically mentioned certain U.S. and European organizations that were involved in such research, including the Harvard School of Public Health, the U.S. Environmental Protection Agency, the American International Health Alliance (AIHA, a health NGO in Russia that receives Global Fund and USG funding), the Karolinian Institute in Sweden, the Swedish Agency for International Development, and the Indian Genome Institute.

¶13. (SBU) AIHA quickly denied that it is involved in any such research or in taking specimens out of Russia. The ban was

also swiftly condemned by Academy of Medical Sciences President Davydov, who noted the devastating impact the ban would have on Russia's on-going scientific collaboration with many Western researchers, including in the United States. Chief Medical Officer Onishchenko was more muted and simply observed that "any civilized country" needs to regulate the import and export of biological specimens for security reasons. Onishchenko's comment, however, failed to explain how an outright ban, rather than regulation, was justified.

¶4. (SBU) Most immediately, the ban will affect basic clinical trials of new drugs run by multinational pharmaceutical companies. There are over 28,000 Russians currently receiving new medicines through clinical trials, and experts value the Russian market for clinical trials at \$100-150 million. During these trials, blood, urine or other biological samples from patients are routinely sent abroad for testing at a single specialized international laboratory, in order to maintain the consistency of data. Glaxo Smith Kline's Moscow office issued a statement saying the ban was a serious blow to domestic health care and would hinder clinical trials in Russia.

¶5. (SBU) Beyond the effect on clinical trials, Russians suffering from leukemia or other blood cancers frequently need bone marrow or other transplants, and blood samples are regularly sent abroad to type the specimen and find a donor match. The ban would also affect more unique programs, like the CDC's Tuberculosis Program and the Arctic Investigations Program, which collaborate with Russian researchers on tracking the drug-resistance of tuberculosis in Russia and the health of Russia's indigenous communities in the Far North.

MOSCOW 00002533 002 OF 003

¶6. (SBU) The ban also seems inconsistent with Russia's long-term goals to establish itself as an international health player. The focus on infectious diseases during Russia's 2006 G8 Presidency included establishing the Vector State Research Center of Virology and Biotechnology as a regional center for influenza and ultimately as a WHO collaborating center for avian influenza. A complex of Russian institutes are also supposed to be established as a regional center for HIV vaccine development. Neither of these international research efforts will be feasible if Russia is not willing to share specimens with the rest of the world.

Pharmaceutical Companies Left Wondering What to Do

¶7. (C) A contact at Merck's Moscow office confirmed the export ban has been in place since May 28, and has left the company perplexed about how to continue its 21 separate clinical trials of new drugs involving 1,500 patients in Russia. The International Association of Pharmaceutical Manufacturers (AIPM) sent a letter to the Russian Federal Surveillance Service for Health and Social Development (Roszdravnadzor) on May 29 asking for clarification on the export ban. Roszdravnadzor is responsible for approving clinical trials in Russia and also is involved in issuing export and import permits for biological specimens, but the health agency has reportedly not yet even seen the text of the export ban issued by the Federal Customs Service.

¶8. (C) The Merck official told us that the conditions for clinical trials have been extremely favorable over the last two years. While Ramil Khabriyev was the head of Roszdravnadzor, the agency was quick to approve such trials, and apparently recognized they benefited not only Russian patients, but also helped stimulate domestic pharmaceutical and medical research. With Khabriyev's firing earlier this year over the financing and supply problems with the government's drug benefits program (Ref A), the representative did not rule out the possibility that domestic

drug makers might be trying to make business more difficult for their international competitors.

¶9. (C) The Health and Social Development Ministry's chief infectious disease specialist told us that the ban would clearly damage international medical collaboration and scientific exchanges. While he felt greater regulation of cross-border transfers of human biological specimens could be justified, he said he believes an outright ban made no sense.

Comment: Not Seeing the Forest for the Trees

¶10. (C) The apparently knee-jerk decision to impose an export ban on human biological specimens suggests lingering paranoia among Russian leaders regarding Western organizations' motives in engaging in international research in Russia. Paranoia that the West is somehow engaged in biological meddling in Russia has also occasionally surfaced during avian influenza outbreaks, when some political figures have made irresponsible statements to the media about the causes of outbreaks (Ref C). An outright export ban is too broad and ultimately unworkable, because it would harm too many infirm Russians, who receive new medicines in clinical trials funded by foreign pharmaceutical companies, or who are seeking life-saving tissue and organ transplants from abroad.

¶11. (C) We suspect the government will have to scale back the ban and instead adopt some form of stricter regulation of the export and import of such specimens. There is recent precedent that cooler heads will prevail and quickly reverse this hasty decision. For instance, a botched drug tender issued by the Health and Social Development Ministry for

MOSCOW 00002533 003 OF 003

expensive AIDS drugs in December 2006 was reversed a month later at a meeting of Russia's National HIV/AIDS Committee following complaints by AIDS activists and the international community (Ref B).

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